


Study Summary Review Outline: Clayton Myers, IB

 3-10-09

**Decision #:** 399095

**DP #:** 359985

**MRID:** 475784-02

**Title:** Evaluate the Speed of Kill of RF-2024B against Ticks and Fleas on Dogs\*

\*an amended final report to replace MRID 475184-12

**Purpose/Objectives:**

The study was designed to evaluate the speed of kill of animal pet topical spot on, RF-2042B, against:

American Dog Tick (ADT) adults—residual adulticidal activity

Cat Flea adults—residual adulticidal activity

**Materials and Methods:**

*Animals:* 16 healthy dogs, 6 males and 10 females from BerTeck, Inc. colony, of varying ages and weights (1-4 years and 22.2-41.5 lbs). Dogs were not treated with any insecticides within four weeks of Day 0. BerTek standard housing and feeding protocols were used. These 16 dogs were chosen from a group of 20 based on pre-treatment qualification. Dogs exhibiting the best levels of flea retention were chosen.

*Test parasites:* Cat Fleas were from an in-house colony, ADT from El Laboratories, Soquel, CA.

Test insecticide treatment matches CSF

*Design:*

2 treatments: a control group (1), and an insecticide treated group (2).

Replicates: 6 dogs in control (group 1) and 10 dogs in insecticide treated (group 2).

Randomization: Dogs were ranked by weight and then listed in that order on a random treatment groups assignment table.

*Dosages:* 3.0 ml for dogs weighing between 15 and 30 lbs, and 6.0 ml for dogs weighing from 31 to 55 lbs. Material administered to each dog along the dorsal line in

approximately 3 equal spots—one between shoulders, in the middle of the back, and at the base of the tail. There was one application to all dogs in group 2 with no re-treatments.

*Infestations:* Cat Fleas (100) were applied to each animal 7 days after treatment. ADT (50 each) were applied to each animal 7 days after treatment. All parasites were placed along the dorsal midline from the animal's head to the base of its tail.

*Data collection:*

Pan counts (from pans placed beneath infested dogs in their cages) of fallen fleas and ticks were conducted approximately 15 min., 30 min., 1 h, 2h, 4h, 8h, 12h, and 24 h after the infestation. Pans were replaced at each count, and fleas and ticks dropping into each pan were scored as live or dead.

Removal counts of fleas and ticks were conducted on day 2 after placement (day 9 after treatment) via finger probing and combing of hair. All fleas and ticks were scored as live or dead.

For all counts, group one was assessed first to avoid cross-contamination of pesticide residues.

*Statistics:* Only descriptive statistics are given. Geometric means were calculated for each group and then % reduction was calculated by comparing the group 2 mean to the control: % reduction =  $([GM\ ctrl - GM\ trt]/GM\ ctrl) * 100$ .

**Study Summary of the Results:**

“Efficacy of the test substance initiated within minutes of the infesting parasite acquiring a treated host.”

After 15 minutes, 38% of infesting fleas and 3.4% of infesting ticks had been eliminated from the treated animals

By 48 hours, all the infesting fleas and >85% of infesting ticks had been eliminated.

**Entomologist's Observations and Discussion**

While ticks are shown to be ‘eliminated’ from the animals beginning at the 15 minute count, this does not support a ‘within minutes’ efficacy claim for ticks.

Flea efficacy is acceptable (100% reduction) within 48 hours of treatment. Tick data are quite variable within group 2, but the overall mean and % reduction are acceptable to support a claim of tick efficacy within 48 hours.

**Observations/Discussion:**

1. Dog qualifications were done only with fleas and not ticks. OPPTS 810.3300 indicates a tick qualification is preferred. Also, only one species of tick was assessed in this study.
2. There was not a very good range of dog weights, with no dogs <24 lbs and no dogs > 42 lbs. More importantly, all the dogs were listed as hounds with short hair. It would have been preferable to have some longer haired dogs and some large dogs that would have required the higher dosage over a larger volume of hair. Titration of dosages appears to be valid, as it is the same as the connected studies on this product, but it would have been preferable to use dogs that fall into the upper and lower bounds of each of the given weight classifications.
3. While the pan counts for ticks show the numbers of ticks that were dislodged from the host, it doesn't document the live/dead status of ticks (the study indicated there were no live fleas found in the pans). They should provide data on the number that were actually dead via knockdown activity to support their claim of "efficacy within minutes for ticks".
4. Parasite placement was along the dorsal midline of each animal, which also happens to be the same area where treatment was applied 7 days prior. This doesn't meet the standard of 'sufficient anatomical distribution' per OPPTS 810.3300. It might have been better to apply the fleas/ticks to other areas of the body to avoid bias toward the most heavily coated hair, especially given the short time frame over which the study was conducted, and the lack of long-haired dogs in the study. The registrant should explain why they used this approach to treatment.
5. The label states "kills more than 90% of fleas in 8 hours," however this data shows only 54.8% flea reduction at 8 hours. 24 hour reduction is only 58.2%. Reduction over 90% (actually 100%) is seen only at the 48 hour hand removal count. Therefore, the data only support the a claim of 'within 48 hours.'
6. The label claims are acceptable except as noted below:

Effective on Indoor and Outdoor dogs—Not acceptable, since dogs were not exposed to outdoor conditions in any of the studies.

[Starts killing fleas and ticks within minutes][Kills more than 90% of fleas in 8 hours]—The first claim is OK if revised to 'within 15 minutes.' The second claim is unacceptable, as 90% of fleas are not killed until 48 hours.